



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/528,691

09/21/2005

Gunnar Leo Karup

Q86966

4613

23373

7590

06/07/2010

SUGHRUE MION, PLLC

2100 PENNSYLVANIA AVENUE, N.W.

SUITE 800

WASHINGTON, DC 20037

EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

06/07/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com

PPROCESSING@SUGHRUE.COM

USPTO@SUGHRUE.COM

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/528,691 | <b>Applicant(s)</b><br>KARUP ET AL. |  |
|                              | <b>Examiner</b><br>Celia Chang       | <b>Art Unit</b><br>1625             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-8 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This is an RCE of SN 10/528,691.

Amendment and remark filed by applicants dated May 6, 2010 have been entered.

Claims 4 and 21 are pending. Claims 9-12 have been canceled. Claims 1-3, 5-8, 13-20 stayed withdrawn from consideration.

2. Claims 4 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The amendment of claim 4 and 21 are considered NEW MATTER.

It is noted that the affidavit filed by Erik Fischer was based on the newest development within the area of analysis techniques which cannot be relied upon as enablement for the claims. In re Hogan 194 USPQ 507; In re Glass 181 USPQ 31.

Please note that enablement must be completed as of the time of filing and cannot be relied on or supplemented by the advancing level of skill in the art subsequent to application date.

In the affidavit no information as to what material was employed for the new measurement, what error was discovered at what time and why the specification as originally filed included the currently claimed product within its four corners. Please note that the product as originally disclosed in claim 4 is DL lactate "hemihydrated" having the XRD of claim 4. The elemental analysis corresponding to a hemihydrate was disclosed. There is no evidence that any error in identifying the "chemical identity" of this product. Please note that the Seddon reference of record, provided state of the art evidence that level of ordinary skill in the art is that "*there should never be any doubt as to their chemical identity*".

A correction of specification is allowed *only when evidence support that an error was at issued*. If the elemental analysis as originally filed concluded in that the molecular formulas are hemihydrate or ¼ hydrate, then how can the same elemental analysis becomes anhydrous?

Art Unit: 1625

Applicants must provide factual evidence that:

1. when was the error discovered;
2. how did it occur;
3. what evidence support that the new formula/product is within the “four corner” of the specification as originally filed.

The correction of example 4 into a product having elemental analysis being  $C_{34}H_{33}NO_7S$  was searched in the chemical abstract and the compounds corresponding to this molecular formula are provided as exhibit I for applicants' convenience. Please note that none of the compounds is a raloxifene lactate (see Exhibit I).

3. The amendment to the specification filed July 14, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Raloxifene DL lactate anhydrous or Raloxifene L-lactate anhydrate.

Applicant is required to cancel the new matter in the reply to this Office Action.

Correction of specification cannot based on new development in techniques. No evidence can be found in the declaration that when, how and what error occurred and when, how and what error was found with factual record to support any correction.

4. A claim to the priority benefit cannot be granted since no antecedent basis for the currently amended claims are found in the priority documents.

5. The rejection of claims 4 and 21 under 35 USC 112 second paragraph and first paragraph of record will be applicable when the new matter is removed and the claims are restored to its original version.

Art Unit: 1625

**A).** Claim 4 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is very confusing as to what is being claimed. Please note that each acid addition salt is a different chemical compound and each solvate or hydrate is an independent and different chemical identify (see Seddon). It is very confusing as how many compounds are being claimed.

In addition, for racemates, there is the crystal of L-raloxifene lactate and D-raloxifene lactate in racemic mixture which will be physical mixing of a D-crystal and a L-crystal. Or it could be a racemic crystal of one D-raloxifene lactate and one L-raloxifene lactate. The two kinds of racemic crystal are distinct and different. It is understood by one having ordinary skill in the crystal art that racemic crystals are well known to be either (i) made of physical mixture of the R-crystal and S-crystal (homochiral crystals) which are separable by mechanical means (see Fasel et al. and Yokota et al.) ; or (ii) made of racemate unit, i.e 1-R and 1-S pair or less ordered ratio (heterochiral crystals, the unit cells are made of both enantiomer, such as ibuprofen, see Zhang et al). There is no clarity as to what does the d-space or  $2\theta$  are drawn to, mixture of homochiral crystal? Or heterochiral crystal of paired R- and S- in the unit cell.

**B).** Claim 4 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is understood by one having ordinary skill in the crystal art that racemic crystals are well known to be either (i) made of physical mixture of the R-crystal and S-crystal (homochiral crystals) which are separable by mechanical means (see Fasel et al. and Yokota et al.) ; or (ii) made of racemate unit, i.e 1-R and 1-S pair or less ordered ratio (heterochiral crystals, the unit cells are made of both enantiomer, such as ibuprofen, see Zhang et al). The claimed DL raloxifene lactate can only be one or the other. The specification provided no support that the d-space or  $2\theta$  of claim 4 are drawn to, mixture of homochiral crystal? Or heterochiral crystal of paired R- and S- in the unit cell.

Art Unit: 1625

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Jun. 1, 2010*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*